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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,647	07/28/2000	Yves Fouillet	GENSET.077AUS	2266

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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/19/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/627,647

Applicant(s)

FOUILLET ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2001 and 22 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 13-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 52-65 and 67-71 is/are rejected.
- 7) ☒ Claim(s) 12 and 66 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634.

Response to Amendment

2. The substitute specification received on 22 February 2002, Paper No. 14, has been entered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 10, 11, 54-62, 64, 65, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Kopp et al.

5. Kopp et al., discloses a device for performing continuous-flow PCR wherein the sample is passed along a channel under pressure and is caused to undergo thermal cycling while flowing. As seen in Fig. 1, the device comprises an inlet basin, and outlet basin as well as fluid communication means whereby reagents can be added (Fig. 1B).

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6. The device is manufactured in a glass chip; see abstract. Such a teaching meets the limitation that "the substrate consists essentially of silicon;" a limitation of claims 10 and 64.
7. Figure 2A depicts results that were detected subsequent to performing the amplification reaction. Such a showing is considered to meet the limitation that the device further comprises a detector for measuring a physicochemical property of a biological sample; a limitation of claims 11 and 65. As seen in Fig. 2A, the sample can be evaluated not only for the presence or absence of specific nucleic acid sequences, but for their size, relative concentrations, etc.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 7-9, 63, 67, 68, 70, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopp et al., in view of Wilding et al. (US Patent 5,498,392). Kopp et al., teach that multiple samples can be present in one channel and that they are separated by a separator comprising buffer; see page 1047, right column first paragraph.

12. See above for the basis of the rejection as it pertains to the disclosure of Kopp et al.

13. Kopp et al., does not disclose their device as having a plurality of pathways, or that the device comprises one temperature regulated zone that is capable of cycling between at least two temperatures; or that the channels are arranged in parallel and that they are rectilinear.

14. Wilding et al., (US Patent 5,498,392) disclose a device for performing PCR wherein channels are manufactured in a silicon or glass chip. As seen in Fig. 2, at least a portion of the channel means are rectilinear. In Fig. 13 one can see that there are a plurality of pathways and that they are arranged in parallel.

15. Wilding et al., column 9, teach explicitly of the device comprising heating and cooling means. Such means is considered to meet the limitation that the device can heat and cool a given region.

16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the device of Wilding et al., with that of Kopp et al., so to allow for

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the processing of multiple samples simultaneously. While Kopp et al., teach via their Fig. 1 that the channel is arranged in parallel, the disclosure of Wilding et al., provides adequate motivation for having multiple channels in parallel arrangement, thereby allowing one to take advantage of the economy of scale. In view of the well-developed nature of the art and the detailed description provided, the ordinary artisan would have been both well motivated and would have had a reasonable expectation of success.

Conclusion

17. Claims 12 and 66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hansen et al., (US Patent 5,508,197) disclose a PCR device that uses a copper block, in combination with an electric coil, for heating water that is in turn use to achieve thermocycling. Hansen et al., teaches away for using a metal block where in column 6 they teach specifically of using materials for the plate holder that have low thermal mass. Column 8 teaches explicitly that applicant prefers the use of polycarbonate over that of metal.

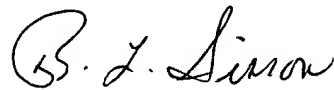
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

21. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
June 13, 2002